

## Column E Explanation

This form is intended as an aid to completing the Column E explanation. It is not an official form and its use is voluntary. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column e explanation must be written so as to be understood by lay persons as well as scientists.

1. Registration Number: **51-R-0082**
2. Number of animals used in this study. **120 per study based on study design**  
**Study AD10YA.195347.BSV - 9 hamsters**
3. Species (common name): **Hamster**
4. Explain the procedure producing pain and/or distress.

**The pain experienced is due to the development of scrapie clinical signs in hamsters. The In Vivo assay is currently the most sensitive assay for scrapie and the only method accepted by regulatory agencies for scrapie. Regulatory agencies are requiring that manufacturers show the efficacy of their manufacturing process in the removal of possible contaminants. Animals must be held until the terminal stage of the disease is observed, which include generalized tremor, abnormality of gait, ataxia and head bobbing. All clinical signs must be confirmed histopathologically (vacuolization of the brain).**

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (for Federally mandated testing, see below)

**See 6. below.**

6. What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specific section number (e.g, APHIS, 9 CFR 113, 102).
  - a. **"Federal Bulletin No. 40, 26 February 1994, German Federal Ministry of Health Guidelines on Safety Measures for Minimizing the Risk of transmission of BSE and Scrapie".**
  - b. **"WHO Consultation of Medical and other Products in Relation to Human and Animal Transmissible Spongiform Encephalopathies" (Geneva 24-26, March, 1997) and OIE Animal Health Code (May 1997) Concerning BSE.**
  - c. **Committee for Proprietary Medicinal Products (CPMP) "Notes for Guidance Minimizing the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Medicinal Products", (1997).**